

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

REMARKS

This Amendment is responsive to the Office Action dated September 27, 2005. Claims 1-10 have been withdrawn pursuant to a Response to a Restriction Requirement. Applicants have amended claims 11, 16 and 25, and have canceled claim 13. Applicants have added claims 31 and 32. Claims 11-12 and 14-32 are pending.

Restriction Under 35 U.S.C. § 121

In a Restriction Requirement, the Examiner restricted claims 1-30 under 35 U.S.C. § 121 as follows:

Group I. Claims 1-10, and

Group II. Claims 11-30.

In a Response to the Restriction Requirement, Applicants elected Group II (Claims 11-30). Applicants affirm this election without traverse.

Claim Objection and Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner objected to claim 16 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner further rejected claim 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants submit that claim 16, as originally presented, did particularly point out and distinctly claim the subject matter that Applicants regard as the invention in a manner that would be understood by one having ordinary skill in the art.

In the interest of furthering prosecution, Applicants have amended claim 16 for purposes of clarification. Applicants submit that claim 16, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. § 112, second paragraph, and that claim 16, as amended, further limits the subject matter of claim 14.

The Examiner's position was that "luminal direction" was undefined, and could be any direction. With the Examiner's interpretation, any rubbing of the luminal surface

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

"is going to be accomplished in a 'luminal direction' since it is done to the luminal surface." Applicants have amended claim 16 to clarify the meaning of the term "luminal direction" in terms of a generally tube-shaped structure of a vascular prosthesis. Applicants' amendment to claim 16 is supported by paragraph [0029] of the specification, for example.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 11, 17, 19, 23 and 24 under 35 U.S.C. § 102(b) as being anticipated by Bruchman et al. (U.S. Pat. No. 5,879,383, hereafter Bruchman). Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the amended claims.

Claims 11 and 17 recite a method pertaining to a vascular prosthesis. Bruchman does not disclose or suggest rubbing a vascular prosthesis. The item being rubbed in Bruchman is a portion of canine artery, which Applicants submit is not a prosthesis, in order to remove cells from the artery. Although Applicants submit that Bruchman does not disclose or suggest rubbing a vascular prosthesis, Applicants have amended independent claim 11 in the interest of moving the claims toward allowance. In particular, independent claim 11 has been amended to include the recitation of dependent claim 13, namely, that the rubbing is "to lift nodes from the luminal surface to define a plurality of recesses," and have canceled claim 13. The Examiner determined that claim 13 was allowable with respect to Bruchman; therefore independent claim 11 as amended is allowable over Bruchman, as is dependent claim 17.

Similarly, independent claim 19 recites applying force to a medical device having at least one surface including expanded polytetrafluoroethylene (ePTFE) "to lift nodes from the surface to define a plurality of recesses." Bruchman clearly does not disclose or suggest lifting nodes from a surface to define a plurality of recesses. Bruchman mentions nothing about rubbing or applying force to affect nodes in any way. Bruchman does not disclose or suggest recesses. The Examiner did not identify any place in Bruchman in which lifting nodes from a surface to define a plurality of recesses is described or

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

suggested. The Examiner apparently overlooked this feature of the invention. Therefore, independent claim 19 is allowable over Bruchman as are dependent claims 23 and 24.

The Examiner also rejected claim 19 under 35 U.S.C. § 102(b) as being anticipated by Martakos et al. (U.S. Pat. No. 5,433,909, hereafter Martakos). Applicants respectfully traverse the rejection. The passages in Martakos cited by the Examiner merely describe stretching ePTFE. According to the Examiner, Martakos discloses applying force to ePTFE to form a medical device. Martakos does not disclose or suggest lifting nodes or defining recesses, as recited in claim 19. The Examiner cited no passage in which Martakos discloses or suggests these features. The Examiner apparently overlooked this feature of the invention; therefore claim 19 is allowable over Martakos.

The Examiner further rejected claims 11-13 and 19-21 under 35 U.S.C. § 102(b) as being anticipated by Okuda et al. (EP 790 042, hereafter Okuda). Applicants respectfully traverse the rejection. The passage of Okuda cited by the Examiner merely discusses inserting a stainless steel rod inside a tube made from ePTFE. Okuda describes insertion of the rod as part of laminating a second tube over the tube on the rod. Like Bruchman and Martakos, Okuda does not disclose or suggest lifting nodes or defining recesses, as recited in independent claims 11 and 19. Further, claim 11 recites rubbing a luminal surface of a vascular prosthesis with a tool to lift nodes from the luminal surface to define a plurality of recesses. The Okuda procedure, by contrast, was directed to affecting the exterior surface, not the luminal surface, of the first tube. Therefore, independent claims 11 and 19, and dependent claims 12-13 and 20-21, respectively, are allowable over Okuda.

The Examiner also rejected claims 25-30 under 35 U.S.C. § 102(b) as being anticipated by Dzau (U.S. Pat. No. 6,352,555, hereafter Dzau). Applicants respectfully traverse the rejection to the extent such rejections may be considered applicable to independent claim 25, as amended, or to claims 26-30, which depend directly or indirectly upon independent claim 25.

Dzau does not disclose or suggest, and the Examiner has acknowledged that Dzau fails to disclose or suggest, one of the features of independent claim 25: "wherein the surface includes recesses defined by nodes lifted from the surface." According to the

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

Examiner, this wherein clause "carries no weight in the absence of any distinguishing structure." As an initial matter, it is improper to simply overlook a "whereby" clause to change the substance of the claimed invention. MPEP 2111.04. Moreover, Applicants submit that a surface including recesses defined by nodes lifted from the surface is a distinguishing structure. Claim 25, as amended, recites that specific distinguishing structure of the surface of the medical device that is to be seeded with cells. Dzau fails to disclose or suggest a structure that includes recesses defined by nodes lifted from the surface, as recited in amended claim 25. Nor does Dzau disclose or suggest seeding such a surface having that specific distinguishing structure. Claim 25 has been amended to clarify that the seeding of cells is related to the surface of the medical device having that specific structure.

The cited references fail to disclose each and every limitation set forth in claims 11-13, 17, 19-21 and 23-30. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 11-13, 17, 19-21 and 23-30 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 14-16 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Bruchman. Applicants respectfully traverse the rejections.

Claims 14-16 and 18 depend upon directly or indirectly upon independent claim 11. Claim 11 is in condition for allowance for the reasons stated above. Claims 14-16 and 18 are therefore also in condition for allowance. Further, the amendment to claim 16 addresses the Examiner's assertion that all rubbing must inherently be in a luminal direction.

In addition, the Examiner's basis for rejection of claims 14-16 and 18 is not in accordance with law. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The Examiner has

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

offered no evidence showing any suggestion or motivation to modify the teachings of Bruchman.

Instead, the Examiner asserts that, even though Bruchman fails to disclose an alternate tool, the choice of a tool is "an obvious matter of design choice." In a proper obviousness determination, the prior art must give a reason or motivation for making the claimed invention. E.g., In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995); In re Oetiker, 24 USPQ2d at 1446. Where the prior art does not teach such a reason or motivation, the Examiner cannot cure this deficiency by using the words "design choice." In re Chu, 36 USPQ2d at 1094-95; see also MPEP 2144.04 (the mere fact that another choice could have been made is not sufficient to support a finding of obviousness; there must be evidence of motivation for making changes). In this instance, the Examiner has given no evidence of any reason or motivation for making the claimed invention.

In re Chu further stands for the proposition that assertion of "design choice" is not appropriate when the technical aspects of the invention do not support the notion of "design choice." 36 USPQ2d at 1095. The Examiner's assertion that "applicant has not disclosed that using the particular brush or brush material provides any advantage or solves any stated problem, or is used for any particular purpose" is not so. Applicants' application includes exactly such a disclosure. Although the application addresses this subject in many places, Applicants direct the Examiner's attention to paragraphs [0062]-[0063], which discuss particular brushes, brush material, and the advantageous results associated with using them:

[0062] In one embodiment of the invention, a 4 millimeter diameter ePTFE vascular graft was everted, placed over a mandrel attached to a tooling jig parallel to the rotational axis of a model lathe via an adjustable loading spring, and the tooling jig fixed to the tool stock of an EMCO Unimat PC model lathe. A wheel brush with densely packed nylon bristles (The Mill-Rose Company, Mentor Ohio, Catalog No. 71810, 1 inch (2.5 cm) diameter, 0.006 inch (150 micrometer) in diameter bristles) was secured in the chuck of a vertical milling head attached to the model lathe. The tool stock was positioned to place the everted graft in contact with the brush attached to the vertical milling head. Uniform translation of the graft across the brush was achieved by attaching the tool stock lead screw to either a 2 rpm or a 10 rpm synchronous motor. While the brush was rotated at speeds ranging from 350 to 2500 rpm, the graft was first

Application Number 10/656,855

Amendment dated December 27, 2005

Responsive to Office Action mailed September 27, 2005

passed in one direction across the brush at 0.075 inches (1.9 mm) per minute (2 rpm synchronous motor) or 0.375 inches (9.5 mm) per minute (10 rpm synchronous motor) with a contact force of 15 gram weight (0.033 lb). The graft was then passed a second time across the rotating brush in the opposite direction with a contact force of 55 gram weight (0.12 lb) over the same range of brush rotation and tool stock translation speeds. The ePTFE may have a wide range of average internodal distances, e.g., from 10 to 200 micrometers between nodes, but good results were obtained with average internodal distances in the range of 30 to 90 micrometers. Vascular grafts of ePTFE are available from a variety of manufacturers.

[0063] In one embodiment of the invention, a wheel brush with densely packed nylon bristles (Mill-rose No. 71810, 1 inch (2.5 cm) in diameter, each bristle about 0.006 inches (150 micrometers) in diameter) was rotated at 350 to 2500 revolutions per minute against a vascular prosthesis made of ePTFE. The prosthesis had been everted so that that luminal surface was more accessible. The brush was moved along the prosthesis transversely at 1100 to 6500 inches per minute (28 to 165 meters per second). Forces in the range of 30 to 100 grams weight (0.066 to 0.22 pounds) were applied between the brush and the luminal surface. The ePTFE may have a wide range of average internodal distances, e.g., from 10 to 200 micrometers between nodes, but good results were obtained with average internodal distances in the range of 30 to 90 micrometers. Vascular grafts of ePTFE are available from a variety of manufacturers.

The Examiner's assertion that Bruchman teaches use of a "brush" is also inaccurate. Bruchman discusses a cotton swab, col. 18, line 61, not a brush comprising bristles as recited in claim 14. Additionally, the Examiner's assertion that Bruchman's procedure and the claimed method "perform the same function of rubbing a luminal surface of a vascular prosthesis" is incorrect. As explained above, Bruchman teaches rubbing a canine artery to remove cells therefrom, not rubbing a vascular prosthesis to lift nodes from the surface to define a plurality of recesses. For at least the reasons discussed above, the rejection of claims 14-16 and 18 is improper and should be withdrawn. Further, the Examiner admits that Bruchman fails to disclose eversion of the prosthesis after rubbing, as recited in claim 18. The Examiner, without any evidence of any motivation, simply concludes that eversion after rubbing would be obvious. Such a rejection is clearly improper. For the above reasons, the rejection of claims 14-16 and 18 are improper and should be withdrawn.

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

The Examiner also rejected claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Okuda. Applicants respectfully traverse the rejection. The applied reference fails to disclose or suggest the inventions defined by Applicants' claim 22, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention. The Examiner admitted that Okuda fails to disclose "a wheel brush comprising bristles," as recited in claim 22, however, the Examiner failed to produce any evidence supporting any suggestion or motivation to modify the teachings of Okuda to arrive at the claimed invention. Instead, the Examiner relied upon unsubstantiated assertions of "design choice" and a failure of the disclosure to "provide[] any advantage, or solve[] any problem, or [be] used for any particular purpose." For the reasons discussed above with respect to claims 14-16 and 18, the rejection of claim 22 is improper and should be withdrawn.

New Claims:

Applicants have added claims 31 and 32 to the pending application, which depend upon independent claims 11 and 19, respectively. No new matter has been added by the new claims, which are supported by paragraph [0053] of the application, for example. None of the references cited by the Examiner disclose or suggest the inventions defined by Applicants' new claims 31 and 32, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. The cited references fail to disclose or suggest rubbing or applying force to a luminal surface in a direction substantially perpendicular to the nodes. Further, independent claims 11 and 19 are in condition for allowance for the reasons given above, and therefore claims 31 and 32, which depend from independent claims 11 and 19, respectively, are in condition for allowance as well.

Application Number 10/656,855
Amendment dated December 27, 2005
Responsive to Office Action mailed September 27, 2005

CONCLUSION

Claims 11-12 and 14-32 in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

27 DECEMBER 2005
SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:

Daniel J. Hanson
Name: Daniel J. Hanson
Reg. No.: 46,757